UNITED STATES PATENT AND TRADEMARK OFFICE

C/C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,235	06/06/2001	Jack W. Szostak	00786/350009	6199

28120 7590 06/17/2005

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,235	SZOSTAK ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S104

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 6 April 2005 in which claims 63 and 65 were amended, claims 24-62 were canceled and claims 77-79 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 16 December 2004 under 35 U.S.C. 112, first paragraph are withdrawn in view of the amendments. The previous indication of allowable subject matter is withdrawn in view of the amendments, which broaden the scope of the claimed invention and necessitate new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 63-79 are under prosecution.

Claim Rejections - 35 USC § 112: Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to puromycin-like compounds and adenine-like compounds. However, the specification does not provide and adequate written description of the claimed invention. The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed

invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement;* Federal Register/ Vol. 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Reduction to practice

The specification does not describe an actual reduction to practice of the claimed invention. The specification defines peptide acceptors in the paragraph spanning pages 20-21 as being a puromycin, puromycin-like, adenine, or adenine-like compound. The specification further provides specific examples of compounds having properties similar to puromycin and/or adenine. However, the specification does not reduce to practice the broadly claimed puromycin-like and/or adenine-like compounds.

Completed by drawings

The specification does not illustrate the broadly claimed puromycin-like and/or adenine-like compounds.

Description of identifying characteristics

The specification has not been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention. The specification defines properties of peptide acceptors in the paragraph spanning pages 20-21. However, the specification does not teach or describe identifying characteristics which show that applicant was in possession of the claimed puromycin-like and/or adenine-like compounds.

For the above reasons, the specification does not provide a written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude the inventor had possession of the claimed invention see *In re Vas-Cath*, Inc. 935F2d. 1555, 1563, 19 USPQ2d 1111,1116

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 63-76 and 78-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Gold et al (U.S. Patent No. 5,843,701, filed 31 January 1992).

Regarding Claim 63, Gold et al disclose a molecule comprising a nucleic acid portion and a protein portion covalently bound to the nucleic acid portion through a peptide acceptor wherein said protein portion is encoded by the nucleic acid portion (e.g. cross-linked through tRNA, Fig. 1 and Column 23, line 61-Column 24, line 14).

Regarding Claim 64, Gold et al disclose the molecule wherein the protein portion comprises two or more amino acids joined by peptide bonds i.e. polypeptide (Column 7, line 64-Column 8, line 15).

Regarding Claim 65, Gold et al disclose a method for constructing the molecule of Claim 63 comprising the steps of preparing a DNA containing a protein coding sequence, transcribing the DNA into RNA, covalently bonding to the 3'end of the protein coding sequence a peptide acceptor and translating the RNA in a cell-free synthesis system (Column 23, line 61-Column 24, line 14). Gold et al specifically teaches the 3' covalently linkage (Column 24, lines 4-10). While they teach the linkage is performed at the end of peptide synthesis, the instant claims do not require the method steps be performed in the order recited. Furthermore, the claims do not require the instant claims do not define the RNA in step (d) as having a protein acceptor at the 3' end. Therefore, Gold et al disclose the instantly claimed method.

Regarding Claim 66, Gold et al disclose the method wherein step (a) comprises synthesizing a DNA primer and DNA template and amplifying the template using the primer and PCR (Column 15, lines 54-65; Column 30, lines 5-10; and Column 34, lines 52-54).

Regarding Claim 67, Gold et al disclose the method wherein the cell-free system is wheat germ or reticulocyte (Column 12, lines 48-54).

Regarding Claim 68, Gold et al disclose a method for in vitro selection and evolution comprising constructing the molecules of Claim 63, selecting one or more of the molecules and using the nucleic acid of the molecules mutagenically construct a second plurality of molecules (Example 6).

Regarding Claim 69, Gold et al disclose the method further comprising selecting one of the second plurality which are different from the first selected molecules i.e. selection following multiple rounds of SPERT (Example 6).

Regarding Claim 70, Gold et al disclose the method wherein the selecting comprises contacting the first plurality of molecules with a target molecule (e.g. gut membrane molecules, Example 6, Column 34, lines 49-51).

Regarding Claim 71, Gold et al disclose the method wherein the selecting comprises contacting the first and second plurality of molecules with a target molecule (e.g. gut

membrane molecules and multiple rounds of SPERT, Example 6, Column 34, line 61-Column 35, line 5).

Regarding Claim 72, Gold et al disclose the method using mutagenic PCR (Column 34, lines 65-67).

Regarding Claim 73, Gold et al disclose a method for assaying protein/protein or protein/nucleic acid interaction, the method comprising constructing the molecules of Claim 63 and determining whether the molecule interacts with another protein or nucleic acid (i.e. partitioning, column 10, lines 34-53).

Regarding Claim 74, Gold et al disclose the method wherein the determining uses an antibody (Column 26, lines 8-31 and Example 10).

Regarding Claim 75, Gold et al disclose the method wherein the determining comprises immunoprecipitation (Column 26, lines 25-27).

Regarding Claim 76, Gold et al disclose the method wherein the determining immunoprecipitation is carried out with a c-myc antibody (Column 26, lines 25-27 and Example 10).

Regarding Claim 78, Gold et al disclose the molecule of Claim 63 wherein the peptide acceptor is a puromycin-like compound i.e. tRNA 2'deoxy-3'amino-adenosine (Column 24, lines 7-10).

Regarding Claim 79, Gold et al disclose the molecule of Claim 63 wherein the peptide acceptor is an adenine-like compound i.e. tRNA 2'deoxy-3'amino-adenosine (Column 24, lines 7-10).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 65-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,258,558. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method of making and selecting nucleic acid-protein complexes. The claim sets differ in that the patent claims further define the method steps of making and selecting. The instant claim language "comprising" encompasses any addition steps in the patent claims. As such, the patent claims are deemed a species of the instantly claimed genus method.

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed methods are obvious in view of the patent methods.

8. Claims 63-64 and 77-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 1-18. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to nucleic acid-protein complexes. The claim sets merely differ in that the patent claims define the peptide acceptor and components of the encoding sequence. The instant claim language "comprising" encompasses any addition elements recited in the patent claims. As such, the patent claims are deemed a species of the

instantly claimed genus method. Therefore the instantly claimed genus complexes are obvious in view of the patent species.

9. Claims 63-64 and 77-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,214,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to protein encoding RNA molecules. The claim sets differ in that the instant claims are further drawn to the encoded protein. However, the patent defines the encoding RNA as being RNA-protein fusions as instantly defined (Abstract of the '553 patent). Therefore the instantly claimed RNA-protein fusions are an obvious embodiment of the patent RNA.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

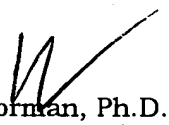
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 15, 2005